IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327 MDL 2327** **JOSEPH R. GOODWIN U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO THE FOLLOWING CASES: **ALL BOSTON SCIENTIFIC CORP. CASES PENDING IN WAVE 13 OF MDL 2327 AND LISTED IN EXHIBIT A OF DEFENSE NOTICE OF ADOPTION**	

PLAINTIFFS' RESPONSE & MEMORANDUM IN OPPOSITION TO DEFENDANT BOSTON SCIENTIFIC CORP.'S MOTION TO EXCLUDE THE GENERAL CAUSATION TESTIMONY OF DR. BRUCE ROSENZWEIG, M.D.

Under Federal Rules of Evidence 702, the Plaintiffs hereby submit this combined response and memorandum of law in opposition to Boston Scientific's Motion to Exclude the General Causation Testimony of Dr. Bruce Rosenzweig, M.D. and Memorandum in Support. *See* Mot. Exclude General Causation Testimony of Dr. Bruce Rosenzweig & Mem. Supp., May 13, 2019, ECF No. 8084. In support, the Plaintiffs show this Court the following:

I. INTRODUCTION

The Plaintiffs retained Dr. Bruce Rosenzweig, M.D. to proffer new general causation opinions for Wave 4 cases involving these Defendant Boston Scientific Corporation ("BSC") products: Advantage, Advantage FIT, Lynx, Obtryx, Solyx, Prefyx, Uphold, and Pinnacle. *See* Exhibit 1, General Expert R. 26 Report of Bruce A. Rosenzweig, M.D., at 4, June 4, 2018. This Court "ha[s] considered Dr. Rosenzweig as a general causation expert [more than] three times in the past, and on each occasion, [this Court] ha[s] admitted his general causation testimony." *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 565 (S.D.W. Va. 2014). Like past decisions, the

Court should deny BSC's motion because Dr. Rosenzweig's general causation testimony is admissible under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

BSC advanced four (4) arguments in its motion and ***only*** challenges a ***select portion*** of Dr. Rosenzweig's opinions. *See* BSC's Mot. & Mem. at 5-9. In the motion's third argument, however, BSC attacks opinions linking cancer to polypropylene, even though Dr. Rosenzweig **did not** disclose cancer opinions in his Rule 26 report and **will not** provide cancer testimony at trial. *See id.* at 7-9 (arguing to exclude cancer opinions in Part C, although admitting none exist in Dr. Rosenzweig's report). Accordingly, the Plaintiffs limit the scope of this response and opposition to the three (3) arguments in BSC's motion that challenge an opinion disclosed in Dr. Rosenzweig's new Rule 26 report for Wave 4.

This Court should reject BSC's other three arguments and deny the motion. ***First***, *Daubert* permits Dr. Rosenzweig to use BSC's internal documents as the basis and to reinforce his opinions about BSC's polypropylene. *See Tyree v. Boston Scientific Corp.*, No. 2:12-cv-08633, 2014 WL 5486694 at *6-7 (S.D.W. Va. Oct. 29, 2014) (holding *Daubert* permits an expert to "testify about . . . internal corporate documents" to "explain[] the basis for his . . . opinions"). ***Second***, Dr. Rosenzweig's "knowledge, training, and experience . . . qualify Dr. Rosenzweig to opine on the design of [BSC devices]," "the polypropylene used to construct [them]," and BSC's warnings. *See Wilkerson v. Boston Scientific Corp.*, No. 2:13-cv-04505, 2015 WL 2087048, at *5-8 (S.D.W. Va. May 5, 2015). ***Third***, Dr. Rosenzweig's qualifications allow him to "us[e] the MSDS—specifically the MSDS statement that polypropylene is incompatible with strong oxidizers—as the basis for his opinion that the mesh at issue should not be used in the vagina." *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2016 WL 4500765, at *4 (S.D.W. Va. Aug. 26, 2016). Thus, the Court should deny BSC's partial-*Daubert* challenge against Dr. Rosenzweig.

II. OPINIONS, QUALIFICATIONS, & METHODOLOGY[1]

A. Opinions.

At the beginning of his report, Dr. Rosenzweig provided a summary of his opinions and conclusions in Wave 4:

A. BSC constructed the Advantage, Advantage Fit, Lynx, Obtryx, Solyx, Prefyx, Pinnacle, and Uphold (collectively, "BSC Mesh Products") with polypropylene that is not suitable for permanent transvaginal implantation to stress urinary incontinence of pelvic organ prolapse; the polypropylene degrades over time, causes chronic foreign body reactions, fibrotic bridging, mesh contracture / shrinkage, fraying, deformation, roping, rolling and curling of the mesh;

B. BSC's Mesh Products lack adequate studies to establish safety and effectiveness for permanent human implantation to treat stress urinary incontinence or pelvic organ prolapse. Without the evidence, BSC's Mesh Products are not suitable for permanent implantation because BSC did not consider relevant and knowable problems and complications associated with implanting its products through the vagina and into the pelvic cavity;

C. BSC disregarded prior experience with the Protegen device when manufacturing the Mesh Products;

D. BSC made public claims about the properties and safety of the Mesh Products to physicians and patient through marketing materials that lack support from the available medical and scientific literature;

E. The Directions For Use ("DFU") BSC provided with all Mesh Products do not fully disclose or adequately warn about the Mesh Products' known or knowable risks, adverse reactions, and characteristics;

F. The severe, debilitating, and life-changing complications associated with the Mesh Products outweighed the products' benefits, which are comparable to the benefits with non-mesh interventions; and

G. BSC polypropylene mesh removal requires a difficult and sometimes impossible surgery with a high likelihood of injuring surrounding tissue.

Ex. 1, Rosenzweig Report at 4-5.

[1] For the Court's convenience, the Plaintiffs attached Dr. Rosenzweig's deposition for his Wave 4 report, although the Plaintiffs do not cite the deposition in this response. *See* Exhibit 2, Dep. of Bruce A. Rosenzweig, M.D. [Wave 4], Aug. 30, 2018.

B. Qualifications.

Dr. Rosenzweig's qualifications satisfy this Court's test under *Daubert* to proffer general causation opinions on BSC's products, including opinions on the products' polypropylene, degradation, designs, suitability for implantation, and warnings. *See Wilkerson*, 2015 WL 2087048, at *5-8 (admitting the opinions after determining Dr. Rosenzweig holds sufficient qualifications to opine on these topics); *see also Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 703-07 (S.D.W. Va. 2014) (finding Dr. Rosenzweig qualified to opine on mesh products' polypropylene, degradation, suitability for implantation, and warnings).

Dr. Rosenzweig received his medical degree in 1984 from the University of Michigan. Ex. 1, Rosenzweig Report at 1. After a pelvic surgery fellowship at the State University of New York-Syracuse and a urogynecology fellowship at UCLA, Dr. Rosenzweig joined the faculty at the University of Illinois-Chicago, where he started a urogynecology program and was the residency program director. *Id.* He is currently a practicing obstetrician/gynecologist and urogynecologist, and an assistant professor of obstetrics and gynecology at Rush University Medical Center. *Id.*

Dr. Rosenzweig has extensive experience with pelvic mesh devices in general and dealing with complications as a result of the BSC's transvaginal mesh devices to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). *Id.* He has performed more than 1,000 surgeries in the pelvic floor, and he conservatively estimated that this number includes 350 surgeries to remove synthetic mesh products due to complications. *Id.* Dr. Rosenzweig has also implanted several polypropylene devices to treat SUI and POP. *Id*. In his practice and research, Dr. Rosenzweig has delved into the problems of degradation and mesh contraction and deformation and chronic inflammation and chronic infection and chronic foreign body reactions. *Id.* at 18-34.

Dr. Rosenzweig's expertise relating to SUI and pelvic mesh products is well recognized. He has published numerous articles and given numerous lectures on topics such as POP and SUI. *Id*. at 1. In fact, his experience and reputation are such that Dr. Rosenzweig was invited by Ethicon to Belgium to meet and train with an inventor of synthetic polypropylene mesh products. *Id.*

C. Methodology.

In his Wave 4 report, Dr. Rosenzweig presented the methodology he used to reach his general causation opinions in this case:

> In formulating my opinions and preparing this report, I reviewed scientific literature, corporate documents from Boston Scientific ("BSC"), documents in the public domain, sample products and depositions of BSC employees. I have also reviewed and relied upon extensive medical and scientific literature concerning these products and other mid-urethral polypropylene mesh slings. All opinions expressed herein are based on my experience, training, knowledge, and the reliance material identified herein. A list of BSC corporate documents and depositions reviewed for this report is attached hereto as Exhibit "B"; all other materials reviewed are listed at the end of this report. All opinions expressed herein are held to a reasonable degree of medical and scientific certainty.

Ex. 1, Rosenzweig Report at 4. The Wave 4 report demonstrates three (3) components that comprise Dr. Rosenzweig's methodology in this case: (1) review and examine medical and scientific literature; (2) review BSC-produced documents, documents in public domain, depositions of BSC employees, and examine BSC's products; and (3) apply first-hand experience, training, knowledge, and education with mesh products to the findings from the reviews and examinations. *See id.* This Court determined Dr. Rosenzweig's three-step methodology satisfies *Daubert's* requirements to proffer general causation opinions on BSC's products:

> . . . the plaintiff offers Dr. Rosenzweig as a **general causation** expert on [a BSC transvaginal mesh product, including] . . . its reaction when implanted in the body, and the possible complications associated with its use
> . . . .
> Dr. Rosenzweig . . . considered . . . [**(1)**] **internal corporate documents** . . . , [**(2)**] incorporate[ed] his **experience**[,] and [**(3**)] cit[ed] to relevant and persuasive **scientific literature**. . . . **This detailed examination of the literature in light of**

his first-hand experience with mesh devices ***satisfies the reliability requirements* of *Daubert*.**

Wilkerson, 2015 WL 2087048, at *5, *7 (emphasis added) (internal citations omitted).

III. STANDARD

Under *Daubert* and Rule 702 of the Federal Rules of Evidence, an expert witness must be qualified by "knowledge, skill, experience, training or education." Fed. R. Evid. 702. An expert witness's testimony must represent "scientific knowledge," which requires opinions to rest upon a foundation that can withstand appropriate validation and provide relevant evidence for the jury's assistance. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). In other words, his testimony must "fit" the case, and there must be a "valid scientific connection to the pertinent inquiry as a precondition to admissibility." *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig*., 2:12-md-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15, 2014), *reconsideration denied*, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014). Courts admit an expert's testimony if the opinions (1) "will help the trier of fact to understand the evidence or to determine a fact in issue," (2) are "based upon sufficient facts or data," (3) are "the product of reliable principles and methods" and (4) result from a method reliably applied "to the facts of the case." Fed. R. Evid. 702; *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999); *Daubert*, 509 U.S. at 597. This Court evaluates and determines whether an expert's principles and methods satisfy the reliability requirements under *Daubert* and Rule 702. *See Daubert*, 509 U.S. at 589. District courts enjoy "considerable leeway" in determining the admissibility of expert testimony. *Kumho*, 526 U.S. at 152.

The *Daubert* analysis ***does not*** analyze opinions or impose an evidentiary burden on the proponent to prove the merits of his opinions. Specifically, district courts "need not determine that the proffered expert testimony is irrefutable or certainly correct" because *Daubert* subjects the merits of an expert's opinions to "testing" by cross-examination, contrary evidence, and instruction

on the burden of proof. *Tyree*, 2014 WL 5486694, at *3 (quoting *U.S. v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (quoting *Daubert*, 509 U.S. at 596)). Rather, because this analysis focuses on methodology, *Daubert* requires the proponent of expert testimony to show he used reliable methods to reach his opinions. *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998); *Tyree*, 54 F. Supp. 3d at 516.

The law requires this Court to apply a flexible approach under Rule 702, *see Daubert*, 509 U.S. at 594, to uphold the general framework of the Rules – favoring admissibility of evidence over non-admissibility. *Id.* at 588. In short, "the rejection of expert testimony is the exception rather than the rule." *U.S. v. Stanley*, No. 12-4572, 2013 WL 3770713 at *1 (4th Cir. July 19, 2013) (internal quotations omitted in the cited quotation). Dr. Rosenzweig proffers testimony that satisfies Rule 702 and *Daubert*. The Plaintiffs respectfully request this Court deny BSC's motion.

IV. ARGUMENT & AUTHORITIES

A. Dr. Rosenzweig May Testify About BSC's Corporate Documents Because *Daubert* Permits Experts To Explain The Basis For Their Opinions.

Daubert permits an expert to "testify about . . . internal corporate documents" to "explain[] the basis for his . . . opinions." *Tyree*, 2014 WL 5486694 at *6-7. In contrast, *Daubert* prohibits an expert to "testify about . . . corporate documents" to prove a "party's knowledge, state of mind, or other matters related to corporate conduct and ethics . . . because opinions on these matters will not assist the jury." *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 670 (S.D.W. Va. 2014). In other words, *Daubert* only bars an expert's testimony about corporate documents if used to prove a corporation's knowledge, state of mind, or corporate conduct and ethics. *See id.* Although this Court recognizes a distinction between permissible and impermissible uses of corporate documents, BSC disregards the distinction to challenge all testimony about BSC's corporate documents.

In *Edwards v. Ethicon, Inc.*, this Court's decision on Dr. Rosenzweig's expert testimony illustrates the permissible uses of internal corporate documents. No. 2:12-cv-09972, 2014 WL 3361923, at *8–9 (S.D.W. Va. July 8, 2014). In that case, Dr. Rosenzweig cited "an internal Ethicon document suggest[ing] that polypropylene mesh was cytotoxic." *Id.* at *9. Dr. Rosenzweig "then opine[d] that Ethicon failed to act as a 'reasonably prudent medical device manufacturer' because it 'failed to inform physicians and their patients about the risk of its mesh being cytotoxic.'" *Id.* (quoting Dr. Rosenzweig's Ethicon report). In other words, Dr. Rosenzweig used the document as a basis for identifying a risk with Ethicon's products – not to prove Ethicon's state of mind. *See id.*

In *Wise v. C.R. Bard, Inc.*, Dr. Raybon's expert testimony also illustrates the permissible use of internal corporate documents. No. 2:12-CV-01378, 2015 WL 521202, at *15 (S.D.W. Va. Feb. 7, 2015). The Court admitted Dr. Raybon's general causation testimony on internal documents in the Bard MDL because the documents "develop[ed] and reinforce[ed] his opinions." *Id.* Under *Edwards* and *Wise*, *Daubert* allows expert testimony on corporate documents if the expert uses the documents to develop, support, or reinforce the expert's opinion. *See id.*

Here, BSC claims Dr. Rosenzweig "regurgitates" internal documents evincing BSC's literature searches, presentations, and internal emails related to clinical studies, the ProteGen device, and public claims. *See* BSC's Mot. & Mem. at 6. BSC also contends, without any analysis, that Dr. Rosenzweig offers "state of mind" opinions in two (2) Parts of his report – Part IV.A.7. and Part IV.C. *See id.* (citing Ex. 1, Rosenzweig Report §§ IV.A.7., IV.C.). In Part IV.A.7 of the report, Dr. Rosenzweig opines, "BSC internal document concerning mesh's defective properties ***are consistent with and support my opinions***." Ex. 1, Rosenzweig Report at 32 (§ IV.A.7.). In Part IV.C. of the report, Dr. Rosenzweig opines, "BSC disregarded prior experience with the

ProteGen device when manufacturing the Advantage, Advantage Fit, Lynx, Obtryx, Solyx, Prefyx, Pinnacle, and Uphold products." *Id.* at 44 (§ IV.C.). BSC argues *Daubert* precludes Dr. Rosenzweig's "regurgitation" and "state of mind" opinions. *See* BSC's Mot. & Mem. at 5-6. The following discussion addresses BSC's challenges in turn.

First, Dr. Rosenzweig uses BSC's literature searches, presentations, and internal emails to support and reinforce his opinions. Although BSC states Dr. Rosenzweig "regurgitates" "internal documents," BSC neglected to cite where Dr. Rosenzweig allegedly "regurgitated" documents for the Court to decipher whether Dr. Rosenzweig's use of the documents was impermissible. *See* BSC's Mot. & Mem. at 6. Regardless, Dr. Rosenzweig uses BSC's literature searches and presentations for sales meetings in Part IV.A.7. as a basis and to reinforce his opinions about the suitability of BSC's polypropylene for permanent, transvaginal implantation. *See* discussion *infra* this Part on Subpart A.7. Likewise, Dr. Rosenzweig uses BSC's internal emails as bases for and to reinforce his opinions about the clinical data for BSC's products and the ProteGen device. *See* Ex. 1, Rosenzweig Report at 34-46. Under *Edwards* and *Wise*, *Daubert* allows Dr. Rosenzweig's testimony because the internal documents "reinforce" and provide an additional "basis" for his opinions. *See Edwards*, 2014 WL 3361923, at *8-9; *Wise*, 2015 WL 521202, at *15.

Next, Dr. Rosenzweig uses BSC documents in Part IV.A.7. of his report to support and reinforce his opinions. In Part IV.A. of his report, Dr. Rosenzweig opines, "BSC constructed [its] products with polypropylene that is not suitable in a permanent transvaginal implant." Ex. 1, Rosenzweig Report at 18. Relying on his experience as a surgeon, knowledge of the pelvic floor, training, and literature review, Dr. Rosenzweig presented the bases for his conclusion about the non-suitability of BSC's polypropylene in six (6) independent subparts:

Subpart	**Non-Suitable Characteristic of BSC's Polypropylene For Use In A Permanent Implant**
§ IV.A.1.	The polypropylene degrades inside the pelvic floor after transvaginal implantation.[2]
§ IV.A.2.	The polypropylene is not meant for humans or the vagina because of strong oxidizing agents in the human pelvic floor.[3]
§ IV.A.3.	The polypropylene induces a chronic foreign body reaction that attacks the mesh device after transvaginal implantation.[4]
§ IV.A.4.	The polypropylene provides a safe harbor for bacteria and bacterial infections after implantation through the non-sterile vagina.[5]
§ IV.A.5.	The polypropylene undergoes fibrosis after transvaginal implantation, encapsulating the implant with rigid plates of scar tissue.[6]
§ IV.A.6.	The polypropylene contracts and shrinks after transvaginal implantation.[7]

For each of the six (6) characteristics, Dr. Rosenzweig also opined on the clinical complications secondary to the characteristic after transvaginal implantation. *See id.* at 18-32.

Then, Dr. Rosenzweig used BSC's documents in Subpart 7 to reinforce and provide additional bases for his conclusions in Subparts 1-6 of Part IV.A. *See id.* at 32-34. For example, Dr. Rosenzweig cited the 2008 Macaluso Report on the scientific literature that BSC produced, finding polypropylene causes complications that result from inadequate pore sizes, shrinkage, contracture, and scarring. *See id.* at 32. The Macaluso Report provides an additional basis to reinforce Dr. Rosenzweig's polypropylene conclusions in Part IV.A.3. about scarring from a foreign body reaction, Part IV.A.5. about pore sizes, fibrotic bridging, and scarring, and Part IV.A.6. about shrinkage and contracture. *See* chart *supra* p. 10 showing the distinct characteristics

[2] Ex. 1, Rosenzweig Report at 18-22.
[3] *Id.* at 22-26.
[4] *Id.* at 26-27.
[5] *Id.* at 27-29.
[6] *Id.* at 29-30.
[7] *Id.* at 30-32.

that make BSC's polypropylene non-suitable for a permanent transvaginal implant. Dr. Rosenzweig cites three (3) additional documents that similarly reinforce and support his conclusions about the characteristics of BSC's polypropylene that make it unsuitable for use in the human body. *See* Ex. 1, Rosenzweig Report at 32-34.

Like the cytotoxicity document in *Edwards* formed the basis of Dr. Rosenzweig's failure to warn opinions, the BSC documents in Subpart A.7. provide a "basis" for Dr. Rosenzweig's opinions about the non-suitable characteristics of the polypropylene in BSC's mesh products. Just as Dr. Raybon used Bard's documents to reinforce his opinions in *Wise*, the BSC documents in Subpart A.7. "reinforce" Dr. Rosenzweig's opinions that, after implantation, BSC's polypropylene (1) degrades, (2) is not meant for humans, (3) induces a chronic foreign body reaction, (4) causes infections, (5) undergoes fibrosis, and (6) shrinks and contracts. Hence, Dr. Rosenzweig uses BSC's internal documents as a basis and to reinforce his opinion that BSC constructed its mesh products with polypropylene that is not suitable as a permanent transvaginal implant. Under this Court's decisions in *Edwards* and *Wise*, *Daubert* allows Dr. Rosenzweig's testimony on BSC's corporate documents because he uses the documents to develop, support, and reinforce his opinions about the suitability of BSC's polypropylene for use in humans. *See Edwards*, 2014 WL 3361923, at *8-9; *Wise*, 2015 WL 521202, at *15.

Finally, Dr. Rosenzweig uses BSC documents in Part IV.C. of his report to support and reinforce his opinions. In Part IV.C. of his report, Dr. Rosenzweig relies on BSC's documents related to the ProteGen device as a basis for his opinions on the complications related to transvaginal mesh products: "[t]he ProteGen experience shows the types of complications that transvaginal mesh made of synthetic materials, like the Mesh Products, can cause after permanent implantation in the human body." Ex. 1, Rosenzweig Report at 45-46. Like *Edwards* and *Wise*,

Dr. Rosenzweig uses BSC's internal documents as a basis and to reinforce his opinions about the complications caused by BSC's POP and SUI products. Under this Court's decisions in *Edwards* and *Wise*, *Daubert* allows Dr. Rosenzweig's testimony on BSC's Protegen documents because he uses the documents to develop, support, and reinforce his general causation opinions. *See Edwards*, 2014 WL 3361923, at *8-9; *Wise*, 2015 WL 521202, at *15. As *Daubert* permits Dr. Rosenzweig to use BSC's documents as bases for his opinions, the Court should deny BSC's motion.

B. Dr. Rosenzweig's Qualifications Allow His Design And Labeling Opinions, As Well As His Testing Opinions.

Dr. Rosenzweig possesses sufficient qualifications under Rule 702 to provide design and warning opinions on transvaginal medical devices. *Wilkerson*, 2015 WL 2087048, at *6, *7-8 (determining Dr. Rosenzweig's "knowledge, training, and experience with product design . . . qualify Dr. Rosenzweig to opine on the design of [BSC devices] and the polypropylene used to construct [them]"); *See also In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D.W. Va. 2013) (ruling that a urogynecologist was qualified to opine on product design and biomaterials because he had "extensive experience with pelvic floor disorders and the use of mesh to treat such disorders"); *Wise*, 2015 WL 521202, at *14 (S.D.W. Va. Feb.7, 2015) (finding urogynecologist qualified to opine on warnings). A urogynecologist qualifies to opine on the design of mesh products through (1) "extensive experience with pelvic floor disorders," and (2) "the use of mesh to treat such disorders." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612; *accord Wilkerson*, 2015 WL 2087048, at *6 (deciding Dr. Rosenzweig qualifies to opine on the design of BSC's mesh products through his extensive career as a pelvic surgeon, training on and performing pelvic procedures, and inventing a pelvic floor device). A urogynecologist's "experience[]" qualifies him to "testify about the risks he perceives that the [product] poses to patients and then opine that the [product's DFU] did not convey those risks." *Wilkerson*, 2015 WL 2087048, at *8 (quoting *Wise*,

2015 WL 521202, at *14). Lastly, Dr. Rosenzweig holds sufficient qualifications to opine on BSC's testing. *See In re C. R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2187, 2018 WL 514753, at *3 (S.D.W. Va. Jan. 23, 2018).

A urogynecologist qualifies to proffer design and warning opinions under Rule 702 even if his qualifications to opine on product testing fall short of *Daubert's* requirements. *Id.* at *6-7. In *Wilkerson*, for example, this Court decided Dr. Rosenzweig's qualifications satisfied Rule 702's requirements for design and warnings opinions on BSC's products, but prohibited opinions on "BSC's product testing." *Id.* at *6-8. Hence, *Wilkerson* demonstrates Daubert's distinction between the qualifications required to opine on product testing and the qualifications required to opine on design or warnings.

Here, BSC **only challenges** Dr. Rosenzweig's opinions on ***three (3)*** of BSC's ***SUI*** devices: "[h]e is unqualified to offer opinions regarding the design and adequacy of warnings for the Advantage, Advantage Fit, and Lynx." *See* BSC's Mot. & Mem. at 7. **Because Dr. Rosenzweig also opines on BSC's Obtryx, Prefyx, Solyx, Pinnacle, and Uphold devices, BSC chose not to challenge these opinions in its *Daubert* motion**. *See* Ex. 1, Rosenzweig Report at 4. Therefore, the following discussion only responds to BSC's challenge against Dr. Rosenzweig's opinions on the Advantage, Advantage Fit, and Lynx devices.

BSC argues the shortcomings in Dr. Rosenzweig's qualifications preclude not only testing opinions, but also design and warnings opinions. *See id.* at 6-7. BSC's argument fails under this Court's decision in *Wilkerson* distinguishing the qualification requirements for testing opinions from the requirements for design and warnings opinions. *Wilkerson*, 2015 WL 2087048, at *6-8. Like in *Wilkerson*, Dr. Rosenzweig's qualifications here permit his opinions on BSC's designs and warnings, even if his qualifications prohibit opinions on BSC's testing. Indeed, Dr. Rosenzweig

holds the same qualifications he held in *Wilkerson* that sufficed for design and labeling opinions on BSC's transvaginal mesh devices. *See also* Ex. 1, Rosenzweig Report at 1. In addition, like in the Bard MDL, Dr. Rosenzweig's qualifies to opine on product testing for BSC's mesh devices. *See In re C. R. Bard*, 2018 WL 514753, at *3. Because Dr. Rosenzweig's qualifications permit his testimony on the designs of and warnings for the Advantage, Advantage Fit, and Lynx devices, as well as product testing opinions on the devices, this Court should deny BSC's motion.

C. Dr. Rosenzweig Possesses Sufficient Qualifications To Proffer Opinions Based On The Material Safety Data Sheet.

A urogynecologist with experience on polypropylene transvaginal mesh devices holds sufficient qualifications to base opinions on the substance of Material Safety Data Sheets ("MSDS") for the polypropylene. *In re Ethicon Inc.*, 2016 WL 4500765, at *4. This Court's decision in the Ethicon MDL illustrates that *Daubert* allows Dr. Rosenzweig to rely on the MSDS "as the basis for his opinion that the mesh at issue should not be used in the vagina." *Id.* There, "Ethicon [sought] to preclude Dr. Rosenzweig from using the MSDS—specifically the MSDS statement that polypropylene is incompatible with strong oxidizers—as the basis for his opinion that the mesh at issue should not be used in the vagina." *Id.* Ethicon contended Dr. Rosenzweig's qualifications precluded testimony based on the MSDS. *Id.* Ethicon's argument failed because "[a] urogynecologist does not need to be an expert in crafting MSDS warnings to use the substance of such warnings in forming opinions about how mesh reacts in the human body." *Id.* This Court's decision demonstrates the sufficiency of Dr. Rosenzweig's qualifications to opine on polypropylene mesh's reaction in the human body based on the substance of MSDSs. *See id.*

Here, BSC challenges Dr. Rosenzweig's qualifications to base his opinions about BSC's polypropylene on the MSDS. *See* BSC's Mot. & Mem. at 9. Although BSC cites a case excluding Dr. Rosenzweig's testing opinions based on the MSDS, Dr. Rosenzweig offers a different opinion

based on the MSDS in this case. *See id.* (citing *Griffin v. Boston Scientific, Inc.*, No. 2:13-cv-11876, 2016 WL 3031700 at *12 (S.D.W. Va. 2016)). Dr. Rosenzweig opines, "BSC constructed [its] products with polypropylene that is not suitable in a permanent transvaginal implant." Ex. 1, Rosenzweig Report at 18. Dr. Rosenzweig supports his opinion about BSC's polypropylene with six (6) bases that demonstrate the material's non-suitable characteristics. *See id.* at 18-34. Amongst the six, Dr. Rosenzweig opines, BSC's polypropylene is not suitable for transvaginal implantation because the polypropylene is not meant for use in the human body. *Id.* at 22-26. Dr. Rosenzweig based the opinion, in part, on the substance of the MSDS for the polypropylene in BSC's POP and SUI devices. *See id.* at 22-23. The MSDS identifies "**strong oxidizing agents**, such as . . . **peroxides**" as "**[i]ncompatib[le]**" with the polypropylene in BSC's devices. *See id.* at 23 (quoting 2007 MSDS) (emphasis added). Similarly, in the Ethicon MDL, "Dr. Rosenzweig . . . us[ed] the MSDS—specifically the MSDS statement that polypropylene is incompatible with strong oxidizers—as the basis for his opinion that the mesh at issue should not be used in the vagina." *In re Ethicon Inc.*, 2016 WL 4500765, at *4.

In this case, Dr. Rosenzweig further details the opinion and basis that is identical to the opinion and basis that was at issue in the Ethicon MDL. Relying on the scientific literature and his knowledge and experience with female pelvic floor and polypropylene mesh devices, Dr. Rosenzweig explains, "oxidation causes the mesh to degrade, crack and break apart." Ex. 1, Rosenzweig Report at 18. Based on the MSDS, the scientific literature, his clinical experience and knowledge, concludes BSC's "Mesh Products will undergo oxidation or degradation inside women" because "the vagina and perivaginal tissues where surgeons implant BSC's Mesh Products are ready sources of **peroxide**." *Id.* at 25 (emphasis added). On these bases, Dr. Rosenzweig opines, "the effect of chemical and biological alterations of polypropylene due to

oxidation can cause the Mesh Products to either fail or undergo significant change such as shrinkage, hardening, breakage, cracking or flaking, all of which are likely to contribute to an increase in the severity and duration of inflammation in the patient."[8] *Id.*

In the Ethicon MDL, Dr. Rosenzweig possessed sufficient qualifications under Rule 702 for the opinion because "[a] urogynecologist does not need to be an expert in crafting MSDS warnings to use the substance of such warnings in forming opinions about how mesh reacts in the human body." *In re Ethicon Inc.*, 2016 WL 4500765, at *4. Because BSC's motion presents the identical issue presented in the Ethicon MDL, Dr. Rosenzweig's qualifications similarly pass Rule 702 scrutiny in this case. Indeed, Dr. Rosenzweig "does not need to be an expert in crafting MSDS warnings to use the substance of such warnings in forming opinions about how mesh reacts in the human body." *Id.* Like Ethicon's argument, BSC's qualification argument fails to preclude Dr. Rosenzweig's opinions based on the MSDS. Because *Daubert* allows Dr. Rosenzweig's opinions about BSC's polypropylene based on the MSDS, this Court should deny BSC's motion.

V. CONCLUSION & PRAYER

For these reasons, the Plaintiffs respectfully request this Court deny BSC's Motion to Exclude the General Causation Testimony of Dr. Bruce Rosenzweig, M.D. In addition, the Plaintiffs request all other and further relief as this Court deems just and proper.

Dated: January 2, 2020

Respectfully submitted,

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[8] Dr. Rosenzweig further opines, "[s]urgeons cannot appropriately conduct a risk-benefit analysis without knowledge of the Mesh Products' risk of oxidation or degradation." *Id.* On all these bases, Dr. Rosenzweig opines, "BSC should have provided the MSDS information to physicians to enable a full and complete risk-benefit analyses with patients." *Id.* at 26.

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CERTIFICATE OF SERVICE

I hereby certify that on January 2, 2020, I electronically filed the foregoing Response and Memorandum with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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